



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/757,646

01/13/2004

Tracee Eidenschink

1001.2263101

3946

28075 7590 09/17/2008  
CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

09/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,646	<b>Applicant(s)</b> EIDENSCHINK ET AL.	
	<b>Examiner</b> Ryan Severson	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15, 21, 22, 24-38 and 51-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 21, 22, 24-38 and 51-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment*

1. The declaration under 37 CFR 1.132 filed 27 May 2008 is sufficient to overcome the 35 U.S.C. 102(e) rejection of the claims based upon Eidenschink et al.

### *Claim Objections*

2. Claims 63-65 appear to improperly depend from claims 51 and 52 and thus are objected to. During a telephone conversation with Mr. Benjamin Nyquist, it was agreed the claim dependency should be as follows: claim 63 depends from claim 62, claim 64 depends from claim 63, and claim 65 depends from claim 62. Further, Examiner had indicated the claims may be in an allowable state, however, in view of the newly cited art to Cox (5,257,974), a rejection on the merits follows. Appropriate correction is required in response to this action correcting the claim dependency.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox (5,257,974).** Cox discloses a balloon catheter (see figure 32) having a balloon with tapered ends (482) and a sheath (460) that is rotatable about the balloon. The sheath also has tapered ends (see figure 31A) that are capable of radially aligning with the balloon tapered portions.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1, 2, 5-9 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974).** Cox discloses a catheter assembly with a balloon catheter (see figure 22) disposed within a rotatable sheath (350). The rotatable sheath has a guidewire housing (the guidewire can pass through any of the bores 368). However, the embodiment shown in figure 22 does not have end portions of the sheath that have a smaller inner diameter than the central portion. Attention is drawn to figure 8 of Cox, which shows a tubular member having a tapered end to present a less traumatic end to the hollow member that enhances the safe advancement of the tubular member in a vessel (see column 9, lines 20-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the ends of the sheath (350 shown in figure 22 of Cox) with tapered ends as in figure 8 to present atraumatic ends of the sheath for insertion and retraction in the blood vessel.

7. Regarding claims 31-38, Cox does not disclose the materials for the sheath as claimed. It would have been obvious to one having ordinary skill in the art to make the sheath of the claimed materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Art Unit: 3731

8. **Claims 3, 4, 15, 21, 22 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) as applied to claims 1 and 62 above, and further in view of Wilson et al. (6,165,195).** Cox does not disclose a stent disposed about the sheath and guidewire housing. Attention is drawn to Wilson et al., who teach the use of a stent disposed about a guidewire assembly (see figure 13D) and balloon to allow the stent to be placed at a point of a bifurcation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have disposed a stent about the guidewire housing and sheath of Cox in the manner taught by Wilson et al. to allow the balloon catheter to deliver a stent to a point of a vessel bifurcation.

9. **Claims 24-29 and 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) in view of Wilson et al. (6,165,195) as applied to claim 15 above, and further in view of Healy et al. (5,670,161).** The combination of Cox and Wilson et al. does not disclose the stent has therapeutic coatings disposed thereon. Attention is drawn to Healy et al., who teach the use of various therapeutic coatings on a stent to speed healing at the site of deployment of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a therapeutic coating on the stent of the combination of Cox and Wilson et al. in the manner taught by Healy et al. to speed healing at the site of deployment of the stent.

Art Unit: 3731

10. **Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) as applied to claim 1 above, and further in view of Lenker et al.**

**(6,350,278).** Cox does not disclose a lubricious coating positioned between the sheath and the shaft. Attention is drawn to Lenker et al., who teach a lubricious material applied between the catheter shaft and the sheath (see Column 9, Lines 58-64) to reduce the amount of friction between the two components. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lubricous coating between the sheath and the catheter shaft in the manner taught by Lenker et al. in the device of Cox to reduce the amount of friction between the two components.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1 and 62 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731